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Attorneys for Defendants
GENERAL ELECTRIC COMPANY and
GE HEALTHCARE INC.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA, SAN FRANCISCO

JOE V. SANCHEZ and SANDRA L.
ROARTY-SANCHEZ,

Plaintiffs,

v.

BAYER HEALTHCARE
PHARMACEUTICALS, INC.;
BAYER HEALTHCARE LLC;
GENERAL ELECTRIC
COMPANY; GE HEALTHCARE,
INC.; TYCO INTERNATIONAL,
INC.; COVIDIEN, INC.; TYCO
HEALTHCARE GROUP, LP;
MALLINCKRODT, INC.; and
BRACCO DIAGNOSTICS, INC.

Defendants.

Case No. CV-08-0973 EMC

**DEFENDANTS GENERAL ELECTRIC
COMPANY'S AND GE HEALTHCARE
INC.'S ANSWER AND AFFIRMATIVE
DEFENSES**

[Jury Trial Demanded]

Defendants GENERAL ELECTRIC COMPANY and GE HEALTHCARE
INC. (incorrectly sued as GE Healthcare, Inc.) ("Defendants") respectfully file this
Answer to Plaintiffs' Original Complaint and Demand for Jury Trial ("Complaint"),
and respond as follows:

NATURE OF THE CASE

1
2 1. Defendants admit that NSF is a rare, acquired systemic disease which
3 may lead to the increased formation of connective tissue in the skin, causing it to
4 become thickened, coarse, and hard, leading to disabling contractures. NSF is
5 progressive and may be fatal. Defendants admit that Omniscan™ is a gadolinium-
6 based contrast agent that is FDA approved for use in the United States in MRI
7 procedures. Defendants further admit that Omniscan™ is approved by the FDA as
8 reasonably safe for its approved uses when utilized properly, in conjunction with
9 the medical judgment of a trained healthcare professional and in accordance with its
10 accompanying warnings, instructions, and contraindications. Defendants expressly
11 deny Paragraph 1 to the extent it purports to expand, or alter the meaning of, or is
12 otherwise inconsistent with the accepted medical and scientific definition of
13 Nephrogenic Systemic Fibrosis also known as Nephrogenic Fibrosing Dermopathy.
14 Except as admitted, Defendants deny the allegations contained in Paragraph 1.

JURISDICTION AND VENUE

15
16 2. Paragraph 2 contains legal conclusions to which no response is
17 required. To the extent a response is deemed to be required, Defendants admit that
18 pursuant to 28 U.S.C. §1332, GE Healthcare Inc. is considered a citizen of both the
19 State of Delaware and the State of New Jersey. Defendants admit that pursuant to
20 28 U.S.C. §1332, General Electric Company is considered a citizen of both the
21 State of New York and the State of Connecticut. Defendants further admit that
22 General Electric Company and GE Healthcare Inc. conduct business in the state of
23 California. Except as admitted, Defendants are without knowledge or information
24 sufficient to form a belief as to the truth of the allegations contained in Paragraph 2
25 and therefore deny the same.

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- 2 -

INTRADISTRICT ASSIGNMENT

3. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 3 and therefore deny the same.

PARTIES

Plaintiffs

4. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 4 and therefore deny the same.

Defendants

5. Paragraph 5 is directed to another defendant and thus requires no response. In the alternative, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 5 and therefore deny the same.

6. Paragraph 6 is directed to another defendant and thus requires no response. In the alternative, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 6 and therefore deny the same.

7. Paragraph 7 is directed to another defendant and thus requires no response. In the alternative, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 7 and therefore deny the same.

8. Paragraph 8 is directed to another defendant and thus requires no response. In the alternative, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 8 and therefore deny the same.

9. Defendants admit that GE Healthcare Inc. distributes, sells, and markets Omniscan™ in the United States in accordance with FDA rules and

1 regulations. Except as admitted, Defendants deny the allegations contained in
2 Paragraph 9.

3 10. Defendants admit that General Electric Company is a New York
4 corporation, with its principal place of business at 3135 Easton Turnpike, Fairfield,
5 Connecticut 06828. Except as admitted, Defendants deny the allegations contained
6 in Paragraph 10.

7 11. Defendants admit that GE Healthcare Inc. is a Delaware corporation,
8 with its principal place of business at 101 Carnegie Center, Princeton, New Jersey,
9 08540. Except as admitted, Defendants deny the allegations contained in Paragraph
10 11.

11 12. Defendants admit that GE Healthcare Inc. distributes, sells, and
12 markets Omniscan™ in the United States in accordance with FDA rules and
13 regulations. Except as admitted, Defendants deny the allegations contained in
14 Paragraph 12.

15 13. Paragraph 13 is directed to another defendant and thus requires no
16 response. In the alternative, Defendants are without knowledge or information
17 sufficient to form a belief as to the truth of the allegations contained in Paragraph
18 13 and therefore deny the same.

19 14. Paragraph 14 is directed to another defendant and thus requires no
20 response. In the alternative, Defendants are without knowledge or information
21 sufficient to form a belief as to the truth of the allegations contained in Paragraph
22 14 and therefore deny the same.

23 15. Paragraph 15 is directed to another defendant and thus requires no
24 response. In the alternative, Defendants are without knowledge or information
25 sufficient to form a belief as to the truth of the allegations contained in Paragraph
26 15 and therefore deny the same.

27 16. Paragraph 16 is directed to another defendant and thus requires no
28 response. In the alternative, Defendants are without knowledge or information

1 sufficient to form a belief as to the truth of the allegations contained in Paragraph
2 16 and therefore deny the same.

3 17. Paragraph 17 is directed to another defendant and thus requires no
4 response. In the alternative, Defendants are without knowledge or information
5 sufficient to form a belief as to the truth of the allegations contained in Paragraph
6 17 and therefore deny the same.

7 18. Paragraph 18 is directed to another defendant and thus requires no
8 response. In the alternative, Defendants are without knowledge or information
9 sufficient to form a belief as to the truth of the allegations contained in Paragraph
10 18 and therefore deny the same.

11 19. Paragraph 19 is directed to another defendant and thus requires no
12 response. In the alternative, Defendants are without knowledge or information
13 sufficient to form a belief as to the truth of the allegations contained in Paragraph
14 19 and therefore deny the same.

15 20. Paragraph 20 is directed to another defendant and thus requires no
16 response. In the alternative, Defendants are without knowledge or information
17 sufficient to form a belief as to the truth of the allegations contained in Paragraph
18 20 and therefore deny the same.

19 21. Defendants are without knowledge or information sufficient to form a
20 belief as to the truth of the allegations contained in Paragraph 21 and therefore deny
21 the same.

22 **FACTS**

23 22. Defendants are without knowledge or information sufficient to form a
24 belief as to the truth of the allegations contained in Paragraph 22 and therefore deny
25 the same.

26 23. Defendants admit that NSF/NFD is a rare, acquired systemic disease
27 which may lead to the increased formation of connective tissue in the skin, causing
28 it to become thickened, coarse, and hard, leading to disabling contractures. NSF is

1 progressive and may be fatal. Defendants expressly deny Paragraph 23 to the
2 extent it purports to expand, or alter the meaning of, or is otherwise inconsistent
3 with the accepted medical and scientific definition of Nephrogenic Systemic
4 Fibrosis also known as Nephrogenic Fibrosing Dermopathy. Except as admitted,
5 Defendants deny the allegations contained in Paragraph 23.

6 24. Defendants deny the allegations contained in Paragraph 24.

7 25. Defendants admit that gadolinium is not an endogenous metal in the
8 human body. Except as admitted, Defendants deny the allegations contained in
9 Paragraph 25.

10 26. Paragraph 26 contains scientific conclusions and opinions that are
11 more properly the subject of expert opinion testimony. To the extent that a
12 response to Paragraph 26 is deemed to be required, Defendants admit that
13 Omniscan™ utilizes a chelated formulation to bind gadolinium ions. Except as
14 admitted, Defendants deny the allegations contained in Paragraph 26.

15 27. Paragraph 27 contains scientific conclusions and opinions that are
16 more properly the subject of expert opinion testimony. To the extent that a
17 response to Paragraph 27 is deemed to be required, Defendants admit that
18 Omniscan™ utilizes a chelated formulation to bind gadolinium ions. Defendants
19 admit that chelating gadolinium facilitates excretion of the complex through the
20 kidneys. Except as admitted, Defendants deny the allegations contained in
21 Paragraph 27.

22 28. Defendants are without knowledge or information sufficient to form a
23 belief as to the truth of the allegations contained in Paragraph 28 and therefore deny
24 the same.

25 29. Defendants deny the allegations contained in Paragraph 29.

26 30. Paragraph 30 contains scientific conclusions and opinions that are
27 more properly the subject of expert opinion testimony. In the alternative,
28 Defendants admit that NSF was first reported in medical literature in 2000,

1 retrospectively referencing a case from 1997. Defendants further admit that the
2 first report of a case of NSF associated with the administration of a gadolinium-
3 based contrast agent appeared in the medical literature in March 2006. Except as
4 admitted, Defendants are without knowledge or information sufficient to form a
5 belief as to the truth of the allegations contained in Paragraph 30 and therefore deny
6 the same.

7 31. Defendants are without knowledge or information sufficient to form a
8 belief as to the truth of the allegations contained in Paragraph 31 and therefore deny
9 the same.

10 32. Defendants are without knowledge or information sufficient to form a
11 belief as to the truth of the allegations contained in Paragraph 32 and therefore deny
12 the same.

13 33. Defendants deny the allegations contained in Paragraph 33.

14 34. Defendants deny the allegations contained in Paragraph 34.

15 35. Defendants deny the allegations contained in Paragraph 35.

16 36. Defendants deny the allegations contained in Paragraph 36.

17 37. Defendants admit that GE Healthcare Inc. issued its first Dear Doctor
18 letter apprising physicians in the United States regarding reports of NSF in
19 association with the administration of gadolinium-based contrast agents on June 6,
20 2006. To the extent the allegations in Paragraph 37 are directed to other
21 defendants, General Electric Company and GE Healthcare Inc. are without
22 knowledge or information sufficient to form a belief as to the truth of the
23 allegations and therefore deny the same. Defendants deny any remaining
24 allegations contained in Paragraph 37.

25 38. Defendants deny the allegations contained in Paragraph 38.

26 39. Defendants deny the allegations contained in Paragraph 39.

27 40. Defendants deny the allegations contained in Paragraph 40.

28 41. Defendants deny the allegations contained in Paragraph 41.

DISCOVERY RULE & FRAUDULENT CONCEALMENT

42. Paragraph 42 contains legal conclusions to which no response is required. In the alternative, Defendants deny the allegations contained in Paragraph 42.

43. Paragraph 43 contains legal conclusions to which no response is required. In the alternative, Defendants deny the allegations contained in Paragraph 43.

FIRST CAUSE OF ACTION

STRICT LIABILITY: FAILURE TO WARN

44. Defendants hereby incorporate their responses to the allegations contained in Paragraphs 1 through 43 as if set forth fully herein.

45. Defendants deny the allegations contained in Paragraph 45.

46. Defendants deny the allegations contained in Paragraph 46.

SECOND CAUSE OF ACTION

STRICT LIABILITY: DESIGN DEFECT

47. Defendants hereby incorporate their responses to the allegations contained in Paragraphs 1 through 46 as if set forth fully herein.

48. Defendants admit that GE Healthcare Inc. distributes, sells and markets Omniscan™ in the United States in accordance with FDA rules and regulations. Defendants further admit that General Electric Company manufactures magnetic resonance machines. Except as admitted, Defendants deny the allegations contained in Paragraph 48.

49. Defendants deny the allegations contained in Paragraph 49.

50. Defendants deny the allegations contained in Paragraph 50.

51. Defendants deny the allegations contained in Paragraph 51.

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THIRD CAUSE OF ACTION

STRICT LIABILITY: FAILURE TO ADEQUATELY TEST

52. Defendants hereby incorporate their responses to the allegations contained in Paragraphs 1 through 51 as if set forth fully herein.

53. Defendants admit that GE Healthcare Inc. distributes, markets and sells Omniscan™ in accordance with FDA rules and regulations. Omniscan™ is approved by the FDA as reasonably safe for its approved uses when utilized properly, in conjunction with the medical judgment of a trained healthcare professional and in accordance with its accompanying warnings, instructions, and contraindications. Except as admitted, Defendants deny the allegations contained in Paragraph 53 and expressly deny that Omniscan™ was marketed directly to consumers.

54. Defendants deny the allegations contained in Paragraph 54.

55. Defendants deny the allegations contained in Paragraph 55.

FOURTH CAUSE OF ACTION

NEGLIGENCE

56. Defendants hereby incorporate their responses to the allegations contained in Paragraphs 1 through 55 as if set forth fully herein.

57. Paragraph 57 contains legal conclusions to which no response is required. To the extent a response is deemed to be required, Defendants deny the allegations contained in Paragraph 57.

58. Defendants deny the allegations contained in Paragraph 58.

59. Defendants deny the allegations contained in Paragraph 59.

60. Defendants deny the allegations contained in Paragraph 60.

61. Defendants deny the allegations contained in Paragraph 61.

62. Defendants deny the allegations contained in Paragraph 62.

63. Defendants deny the allegations contained in Paragraph 63.

FIFTH CAUSE OF ACTION

NEGLIGENT MISREPRESENTATION

64. Defendants hereby incorporate their responses to the allegations contained in Paragraphs 1 through 63 as if set forth fully herein.

65. Defendants deny the allegations contained in Paragraph 65.

66. Defendants admit that Omniscan™ is approved by the FDA as reasonably safe for its approved uses when utilized properly, in conjunction with the medical judgment of a trained healthcare professional and in accordance with its accompanying warnings, instructions, and contraindications. Except as admitted, Defendants deny the allegations contained in Paragraph 66.

67. Defendants deny the allegations contained in Paragraph 67.

68. Defendants deny the allegations contained in Paragraph 68.

69. Defendants deny the allegations contained in Paragraph 69.

SIXTH CAUSE OF ACTION

FRAUD

70. Defendants hereby incorporate their responses to the allegations contained in Paragraphs 1 through 69 as if set forth fully herein.

71. Defendants deny the allegations contained in Paragraph 71.

72. Defendants deny the allegations contained in Paragraph 72.

73. Defendants deny the allegations contained in Paragraph 73.

74. Defendants deny the allegations contained in Paragraph 74.

75. Defendants deny the allegations contained in Paragraph 75.

76. Paragraph 76 contains legal conclusions to which no response is required. In the alternative, Defendants deny the allegations contained in Paragraph 76.

77. Defendants deny the allegations contained in Paragraph 77.

78. Defendants deny the allegations contained in Paragraph 78.

79. Defendants deny the allegations contained in Paragraph 79.

80. Defendants deny the allegations contained in Paragraph 80.

SEVENTH CAUSE OF ACTION

FRAUD: CONCEALMENT, SUPPRESSION OR

OMISSION OF MATERIAL FACTS

81. Defendants hereby incorporate their responses to the allegations contained in Paragraphs 1 through 80 as if set forth fully herein.

82. Defendants deny the allegations contained in Paragraph 82.

83. Defendants deny the allegations contained in Paragraph 83.

84. Defendants deny the allegations contained in Paragraph 84.

EIGHTH CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY

85. Defendants hereby incorporate their responses to the allegations contained in Paragraphs 1 through 84 as if set forth fully herein.

86. Paragraph 86 contains legal conclusions to which no response is required. To the extent a response is deemed to be required, Defendants admit that Omniscan™ is approved by the FDA as reasonably safe for its approved uses when utilized properly, in conjunction with the medical judgment of a trained healthcare professional and in accordance with its accompanying warnings, instructions, and contraindications. Except as admitted, Defendants deny the allegations contained in Paragraph 86.

87. Defendants deny the allegations contained in Paragraph 87.

88. Defendants deny the allegations contained in Paragraph 88.

NINTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY

89. Defendants hereby incorporate their responses to the allegations contained in Paragraphs 1 through 88 as if set forth fully herein.

90. Paragraph 90 contains legal conclusions to which no response is required. To the extent a response is deemed to be required, Defendants admit that Omniscan™ is approved by the FDA as reasonably safe for its approved uses when

utilized properly, in conjunction with the medical judgment of a trained healthcare professional and in accordance with its accompanying warnings, instructions, and contraindications. Except as admitted, Defendants deny the allegations contained in Paragraph 90.

91. Defendants deny the allegations contained in Paragraph 91.

92. Defendants deny the allegations contained in Paragraph 92.

93. Defendants deny the allegations contained in Paragraph 93.

TENTH CAUSE OF ACTION

VIOLATION OF ARIZONA CONSUMER PROTECTION STATUTES

94. Defendants hereby incorporate their responses to the allegations contained in Paragraphs 1 through 93 as if set forth fully herein.

95. Defendants deny the allegations contained in Paragraph 95(a)-(g).

96. Defendants deny the allegations contained in Paragraph 96.

ELEVENTH CAUSE OF ACTION

LOSS OF CONSORTIUM

97. Defendants hereby incorporate their responses to the allegations contained in Paragraphs 1 through 96 as if set forth fully herein.

98. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 98 and therefore deny the same.

99. Defendants deny the allegations contained in Paragraph 99.

RELIEF REQUESTED

Defendants deny that Plaintiffs are entitled to any of the relief requested.

Defendants deny each and every statement, allegation, and averment contained in the Complaint that has not been expressly admitted above.

AFFIRMATIVE DEFENSES

Discovery and investigation may reveal that one or more of the following additional defenses are available to Defendants in this matter. Defendants

1 accordingly assert the following defenses. Upon completion of discovery, if the
 2 facts warrant, Defendants may withdraw any of these defenses as may be
 3 appropriate. Defendants further reserve the right to amend this Answer to assert
 4 additional defenses and other claims as discovery proceeds. Further answering, and
 5 by way of additional defense, Defendants state as follows:

6 **FIRST AFFIRMATIVE DEFENSE**

7 The Complaint fails to state facts sufficient to constitute a cause of action
 8 and otherwise fails to state a claim upon which relief may be granted.

9 **SECOND AFFIRMATIVE DEFENSE**

10 Plaintiffs' claims are barred, in whole or in part, by the applicable statute of
 11 limitations, including but not limited to Cal. Code of Civil Procedure former § 340,
 12 subd. 3, or in the alternative, Cal. Code of Civil Procedure §§ 335.1, 340.5, 340.8
 13 and/or 343.

14 **THIRD AFFIRMATIVE DEFENSE**

15 If Plaintiffs sustained the injuries or incurred the expenses as alleged, and if
 16 Plaintiff Joe V. Sanchez was administered Omniscan™, both of which are
 17 expressly denied, said injuries or expenses were caused by the unforeseeable
 18 alteration, improper handling, or other unforeseeable misuse of the Omniscan™ by
 19 people not within Defendants' control, including but not limited to Plaintiffs or
 20 their healthcare providers' failure to follow warnings and/or failure to follow
 21 instructions, and if the Omniscan™ had not been subjected to use in such an
 22 improper and unintended
 23 manner, Plaintiffs' damages would have been avoided.

24 **FOURTH AFFIRMATIVE DEFENSE**

25 Defendants specifically plead all defenses under the California Commercial
 26 Code now existing or which may arise in the future including, but not limited to,
 27 the defense that Plaintiffs' claims of breach of warranty, express or implied, are
 28 barred by the applicable provisions of the California Commercial Code.

1 **FIFTH AFFIRMATIVE DEFENSE**

2 Plaintiffs' claims are barred because the Omniscan™, if used, was neither
3 defective nor unreasonably safe, and was reasonably fit for its intended use. The
4 warnings and instructions accompanying the product at issue at the time of the
5 occurrence or injuries alleged by Plaintiffs were legally adequate warnings and
6 instructions.

7 **SIXTH AFFIRMATIVE DEFENSE**

8 Defendants owed no duty to Plaintiffs, and in any event, violated no duty
9 that it may have owed to Plaintiffs.

10 **SEVENTH AFFIRMATIVE DEFENSE**

11 Plaintiffs' treating physicians and health care providers stood in the position
12 of a learned intermediary between Defendants and Plaintiffs. Any warnings that
13 Defendants gave were transmitted to the prescribing physicians and/or health-care
14 providers. Defendants' only obligation is to warn the prescribing physician and/or
15 health-care providers and said obligation was fulfilled. Plaintiffs' claims against
16 Defendants accordingly are barred in whole or in part by the learned intermediary
17 doctrine and/or sophisticated user.

18 **EIGHTH AFFIRMATIVE DEFENSE**

19 Plaintiffs' claims are barred in whole or in part by the doctrines of laches,
20 waiver and estoppel.

21 **NINTH AFFIRMATIVE DEFENSE**

22 Any and all injuries suffered by Plaintiffs, the fact of which is expressly
23 denied by Defendants, were the direct and proximate result of sensitivities, medical
24 conditions, reactions and/or idiosyncrasies peculiar to Plaintiff Joe V. Sanchez that
25 were unknown, unknowable or not reasonably foreseeable to these Defendants, and
26 not as a direct and proximate result of wrongful conduct on the part of the
27 Defendants, the fact of which is expressly denied by the Defendants.

28 ///

1 **TENTH AFFIRMATIVE DEFENSE**

2 No act or omission of these Defendants was a substantial factor in bringing
3 about the alleged injuries of Plaintiffs, nor was any such act or omission a
4 contributing cause thereof, and any alleged acts or omissions of these Defendants
5 were superseded by the acts or omissions of others, including Plaintiffs, which
6 were the independent, intervening, unforeseeable, or superseding and proximate
7 cause of any injury, damage or loss sustained by Plaintiffs.

8 **ELEVENTH AFFIRMATIVE DEFENSE**

9 Plaintiffs have failed to join all indispensable parties; as a result of such
10 failure to join, complete relief cannot be accorded to those already parties to the
11 action and will result in prejudice to the Defendants in any possible future
12 litigation.

13 **TWELFTH AFFIRMATIVE DEFENSE**

14 The manufacture, distribution and sale of the pharmaceutical product
15 referred to in the Complaint was at all times in compliance with all federal
16 regulations and statutes, and Plaintiffs' causes of action are preempted.

17 **THIRTEENTH AFFIRMATIVE DEFENSE**

18 To the extent that Plaintiffs assert claims based on the Defendants' alleged
19 adherence or lack of adherence to and compliance with applicable federal laws,
20 regulations and rules, such claims are preempted by federal law under the
21 Supremacy Clause of the United States Constitution.

22 **FOURTEENTH AFFIRMATIVE DEFENSE**

23 Plaintiffs are barred from recovering against Defendants because Plaintiffs'
24 claims are preempted in accordance with the Supremacy Clause of the United
25 States Constitution and by the Federal Food, Drug and Cosmetics Act, 21 U.S.C.
26 301, et. Seq. ("FDCA"), and regulations promulgated thereunder, with the
27 regulations promulgated by the Food and Drug Administration ("FDA") to
28 implement the FDCA, with the purposes and objectives of the FDCA and the

1 FDA's implementing regulations, and with the specific determinations by the FDA
2 specifying the language that should be used in the labeling accompanying the
3 subject pharmaceutical product.

4 **FIFTEENTH AFFIRMATIVE DEFENSE**

5 Plaintiffs' claims are barred in whole or in part by the deference given to the
6 primary jurisdiction of the FDA over the subject pharmaceutical product at issue
7 under applicable federal laws, regulations and rules.

8 **SIXTEENTH AFFIRMATIVE DEFENSE**

9 Plaintiffs' claims are barred in whole or in part because there is no private
10 right of action concerning matters regulated by the FDA under applicable federal
11 laws, regulations and rules.

12 **SEVENTEENTH AFFIRMATIVE DEFENSE**

13 Plaintiffs' claims are barred in whole or in part because the manufacture,
14 labeling and sale of Omniscan™ was and is controlled by federal law, and the
15 Defendants at all relevant times complied with applicable statutes and with the
16 requirements of the FDA.

17 **EIGHTEENTH AFFIRMATIVE DEFENSE**

18 If any pharmaceutical product manufactured or sold by Defendants was
19 involved in the incident alleged in the Complaint herein, which Defendants deny,
20 then and in that event, said pharmaceutical product was not defective at the time
21 that it left the control of the Defendants.

22 **NINETEENTH AFFIRMATIVE DEFENSE**

23 Plaintiffs' claims are barred in whole or in part because the products,
24 methods, standards, and/or techniques used in manufacturing, designing,
25 marketing, and/or labeling were in accordance with the state of the art at the time
26 they were manufactured, designed, marketed, and/or labeled.

27 **TWENTIETH AFFIRMATIVE DEFENSE**

28 The pharmaceutical product at issue was fit and proper for its intended

1 purpose and the utility of the subject pharmaceutical product at issue outweighs
2 any possible risk inherent in the use of the subject pharmaceutical product.

3 **TWENTY-FIRST AFFIRMATIVE DEFENSE**

4 Plaintiffs' claims against Defendants are barred under § 6(c) of the
5 Restatement (Third) of Torts: Products Liability.

6 **TWENTY-SECOND AFFIRMATIVE DEFENSE**

7 Plaintiffs' strict liability claims are barred by the unavoidably dangerous
8 product defense in Comment k to § 402A of the Restatement (Second) of Torts.

9 **TWENTY-THIRD AFFIRMATIVE DEFENSE**

10 Plaintiffs' claims are barred in whole or in part because Defendants provided
11 adequate "direction or warnings" as to the use of the subject pharmaceutical
12 product at issue within the meaning of Comment j to § 402A of the Restatement
13 (Second) of Torts.

14 **TWENTY-FOURTH AFFIRMATIVE DEFENSE**

15 Plaintiffs' claims are barred in whole or in part because the pharmaceutical
16 product at issue "provides net benefits for a class of patients" within the meaning
17 of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

18 **TWENTY-FIFTH AFFIRMATIVE DEFENSE**

19 Plaintiffs' claims are barred under § 4, et. seq., of the Restatement (Third) of
20 Torts: Products Liability.

21 **TWENTY-SIXTH AFFIRMATIVE DEFENSE**

22 Plaintiffs' claims are barred in whole or in part because all acts or
23 omissions, if any, by these Defendants (or their agents or representatives) were
24 privileged or justified and any claim based thereon is barred.

25 **TWENTY-SEVENTH AFFIRMATIVE DEFENSE**

26 To the extent that Plaintiffs' claims are based on a theory providing for
27 liability without proof of causation, the claims violate Defendants' rights under the
28 United States Constitution.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

Any warranties made by Defendants to Plaintiffs were disclaimed.

TWENTY-NINTH AFFIRMATIVE DEFENSE

Any claim for breach of express warranty must fail because Plaintiffs failed to allege any representation about the product at issue giving rise to an express warranty.

THIRTIETH AFFIRMATIVE DEFENSE

Any claim for breach of implied warranty fails because the product at issue was used for its ordinary purpose.

THIRTY-FIRST AFFIRMATIVE DEFENSE

Plaintiffs' breach of warranty claims are barred because there is a lack of privity between Plaintiffs and Defendants. Moreover, Plaintiffs failed to notify Defendants of any alleged breach of warranty within a reasonable time after she discovered or should have discovered any such alleged breach and is therefore barred from recovery on such claims.

THIRTY-SECOND AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part because Plaintiffs failed to mitigate their damages, if any.

THIRTY-THIRD AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part because Plaintiffs assumed the risk of injury, if any, associated with the use of the product.

THIRTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiffs' damages, if any, are not recoverable because they are legally too remote, indirect and speculative.

THIRTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiffs' damages, if any, were the result of pre-existing medical and/or health conditions unrelated to any conduct of, or product manufactured, distributed or introduced into interstate commerce by Defendants.

THIRTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiffs' claims based on inadequate warnings are barred even if the Defendants failed to provide adequate warnings with respect to know or potential dangers or risks associated with the use of Omniscan™, which Defendants expressly deny, because physicians prescribing Omniscan™ either knew or should have known of the potential or known dangers or risks, and there is no duty to warn members of a profession against dangers known or which should be known to members of the profession.

THIRTY-SEVENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part to the extent Plaintiffs have released, settled, entered into an accord and satisfaction, or otherwise compromised their claims.

THIRTY-EIGHTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred or reduced by Plaintiffs' contributory and/or comparative negligence and/or contributory and/or comparative fault.

THIRTY-NINTH AFFIRMATIVE DEFENSE

Plaintiffs have failed to allege fraud and/or deceit with particularity.

FORTIETH AFFIRMATIVE DEFENSE

To the extent Plaintiffs' claims relate to Defendants' advertising, marketing, public statements, lobbying, or other activities protected by the First Amendment to the United States Constitution and the California Constitution, such claims are barred.

FORTY-FIRST AFFIRMATIVE DEFENSE

Plaintiffs' claims and recovery are barred, reduced and/or limited pursuant to applicable constitutional, statutory and common law regarding limitations of awards and recovery.

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FORTY-SECOND AFFIRMATIVE DEFENSE

Defendants' liability, if any, for non-economic loss is limited to its equitable share, determined in accordance with the relative culpability of all persons or entities contributing to Plaintiffs' total non-economic loss, if any, including those over whom Plaintiffs could have obtained personal jurisdiction with due diligence.

FORTY-THIRD AFFIRMATIVE DEFENSE

Any verdict or judgment that might be recovered by Plaintiffs must be reduced by those amounts that have indemnified, or will in the future, with reasonable certainty, indemnify Plaintiffs in whole or in part for any past or future claimed economic loss from any collateral source such as insurance, social security, workers' compensation or employee benefit program.

FORTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiffs' non-economic loss must be allocated in accordance with the provision of Cal. Civil Code § 1431.1 ("Proposition 51").

FORTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiffs' Complaint fails to state a claim upon which relief can be granted for punitive or exemplary damages.

FORTY-SIXTH AFFIRMATIVE DEFENSE

Defendants deny any conduct for which punitive or exemplary damages could or should be awarded and deny that Plaintiffs have produced evidence sufficient to support or sustain the imposition of punitive damages pursuant to the applicable standard(s) of proof.

FORTY-SEVENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims seeking punitive or exemplary damages violate the substantive and procedural aspects of the Due Process Clause of the Fifth and Fourteenth Amendments to the United States Constitution, the Equal Protection Clause, the Excessive Fines Clause, the Commerce Clause and the cognate provisions of the California Constitution.

1 **FORTY-EIGHTH AFFIRMATIVE DEFENSE**

2 Any award of punitive or exemplary damages is barred to the extent that it is
3 inconsistent with the standards and limitations set forth in *BMW of North America,*
4 *Inc. v. Gore*, 517 U.S. 559, 134 L.Ed. 2d 809, 116 S.Ct. 1589 (1996), *State Farm*
5 *Mutual Automobile Insurance Co. v. Campbell*, 538 U.S. 408 (2003) and *Phillip*
6 *Morris USA v. Williams*, 127 S.Ct. 1057 (2007).

7 **FORTY-NINTH AFFIRMATIVE DEFENSE**

8 No act or alleged omission of Defendants was vile, base, willful, malicious,
9 wanton, oppressive or fraudulent, or done with a conscious disregard for the health,
10 safety and rights of Plaintiffs and others, or with actual malice, fraud or oppression
11 as defined in Cal. Civil Code § 3294, and Plaintiffs' Complaint fails to state a claim
12 upon which relief can be granted for punitive or exemplary damages. Plaintiffs'
13 Complaint seeks damages in excess of those permitted by law. Defendants assert
14 any statutory or judicial protection from punitive or exemplary damages that is
15 available under the applicable law, and any award of punitive or exemplary
16 damages is barred.

17 **FIFTIETH AFFIRMATIVE DEFENSE**

18 Any verdict or judgment that might be recovered by Plaintiffs must be
19 reduced by those amounts that have indemnified, or will in the future, with
20 reasonable certainty, indemnify Plaintiffs in whole or in part for any past or future
21 claimed economic loss from any collateral source such as insurance, social security,
22 workers' compensation or employee benefit program.

23 **FIFTY-FIRST AFFIRMATIVE DEFENSE**

24 Defendants have not engaged in any business practices which are "unfair" as
25 that term is defined by Cal. Business & Professions Code § 17200 or 17500, et seq.

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FIFTY-SECOND AFFIRMATIVE DEFENSE

Defendants' conduct has been deemed lawful, and thus, Plaintiffs' claims for alleged violations of Arizona's Consumer Protection Statutes as codified in Ariz. Rev. Stat. Ann. § 44-1521, et seq. ("CPS claims") are barred as a matter of law.

FIFTY-THIRD AFFIRMATIVE DEFENSE

Defendants have not engaged in any conduct which offends an established public policy or is immoral, unethical, oppressive, unscrupulous or substantially injurious to consumers, and thus, Plaintiffs' CPS claims are barred as a matter of law.

FIFTY-FOURTH AFFIRMATIVE DEFENSE

Defendants' conduct is protected by state and federal safe harbor provisions, and thus, Plaintiffs' CPS claims are barred as a matter of law.

FIFTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiffs have failed to state a cause of action for violations of Arizona's Consumer Protection Statutes as codified in Ariz. Rev. Stat. Ann. § 44-1521, et seq. because Omniscan™ is not directly distributed, sold or marketed to consumers or the public.

FIFTY-SIXTH AFFIRMATIVE DEFENSE

Punitive damages are not recoverable in a claim for violations of Arizona's Consumer Protection Statutes as codified in Ariz. Rev. Stat. Ann. § 44-1521, et seq.

FIFTY-SEVENTH AFFIRMATIVE DEFENSE

Any imposition of liability under Arizona's Consumer Protection Statutes as codified in Ariz. Rev. Stat. Ann. § 44-1521, et seq. without a finding of causation, reliance and actual harm is unconstitutional and violative of Defendants' due process rights.

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FIFTY-EIGHTH AFFIRMATIVE DEFENSE

Plaintiffs' strict liability design defect claims are barred as a matter of law as set forth in *Brown v. Superior Court* (1988) 44 Cal.3d 1049, 1061.

FIFTY-NINTH AFFIRMATIVE DEFENSE

Plaintiffs' strict liability (failure to adequately test) claims are barred as a matter of law as set forth in *Brown v. Superior Court* (1988) 44 Cal.3d 1049, 1061.

SIXTIETH AFFIRMATIVE DEFENSE

Plaintiffs have failed to allege negligent misrepresentation with particularity.

SIXTY-FIRST AFFIRMATIVE DEFENSE

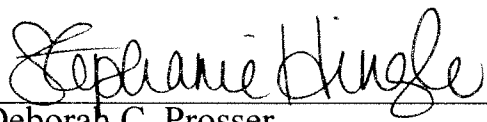
Plaintiffs have failed to allege fraudulent concealment and/or omission with particularity.

WHEREFORE, Defendants General Electric Company and GE Healthcare Inc. pray as follows:

1. That Plaintiffs take nothing by way of their Complaint;
2. That judgment be entered in favor of Defendants;
3. That Defendants be awarded their costs of suit;
4. That Defendants be awarded their attorneys' fees incurred herein; and
5. For such other and further relief as the Court deems appropriate.

Dated: March 11, 2008

KUTAK ROCK LLP

By: 
Deborah C. Prosser
Stephanie A. Hingle
Attorneys for Defendants
GENERAL ELECTRIC COMPANY
and GE HEALTHCARE INC.